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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,565	08/14/2001	Jean-Francois Barault	ETH1475	9842
27777	7590	04/30/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,565

Applicant(s)

BARAULT, JEAN-FRANCOIS

Examiner

Bradford C Pantuck

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 27, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-08-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 14, 15, 18, 22, 24, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,497,650 to Nicolo. Regarding independent Claim 18, Nicolo discloses a mesh-like implant, according to the claimed invention. Nicolo's implant (12) is made out of mesh [Column 4, lines 16-18; Fig. 2a], and has a reinforced zone (14) in a central area of the implant and a peripheral area. Figure 4 shows the implant, and the reinforced zone (14), which extends *radially* from the central part of the implant to a peripheral part of the implant. The reinforced zone has a smaller pore size on average than the peripheral area. The reinforced zone is composed of two layers—a layer of the material that composes the implant in general (12) and a layer of reinforcing material (14) that has a very small pore size. The pore size of the mesh reinforcing material (14) is very small ["submicronal"] so as to prevent body tissue from penetrating the pores and growing into the mesh [Column 4, lines 45-53]. Nicolo's reinforced zone (14) is wider at the edge of the implant than in the central area [see Attachment A from previous office action]. *Nicolo's reinforced zone extends in at least two radial directions from the central area to the edge of the implant [see Attachment B].*
2. Regarding Claim 22, Nicolo discloses a mesh-like implant that can be weft-knitted or warp-knitted. Describing his mesh fabric prosthesis, in Column 4, lines 38-

42, Nicolo says that “woven, molded and other *suitable methods of forming prosthetic mesh materials* may be employed.” It is well known in the art of making surgical mesh that weft knitting and warp knitting are common ways of making surgical mesh, as demonstrated by U.S. Patent No. 6,391,060 to Ory [Column 3, lines 50-59].

3. Regarding Claim 24, Nicolo discloses an implant, in which the reinforced zone is made by attaching a first weft-knitted or warp-knitted mesh to a second weft-knitted or warp-knitted mesh, and the peripheral area of the implant is that portion of the second mesh that is not covered by the first mesh. The reinforced zone [the area covered by and including the first mesh (14)] can be warp or weft-knitted, as explained above with reference to Claim 22. The two meshes are attached to each other [Column 6, lines 20-28].
4. Regarding Claim 25, Nicolo discloses the invention, as claimed. Reinforcing element (14) overlying mesh (12) can be said to reinforce the central part of the prosthesis as well as reinforcing the prosthesis radially, as the reinforced area spreads from the center of the implant to its outer edge [see Fig.2a].
5. Regarding Claims 13 and 15, Nicolo discloses an implant made out of resorbable material [Column 4, lines 35-39, and 63-65]. To “resorb” and to “absorb” mean essentially the same thing: to dissolve and assimilate.
6. Regarding Claim 14, the resorbable material of Nicolo can be a copolymer of lactide and glycolide, otherwise known as VICRYL [Column 4, lines 35-39].

7. Claims 18 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,391,060 to Ory et al. Regarding Claim 18, Ory discloses a mesh-like implant (1) with a mesh-like basic structure (1a) and a reinforced zone (inside of red line in Fig. 4 in previous Office Action) in a central area of the basic structure. The reinforced zone—covered by “additional covering panel 9”—(inside red lines) extends in at least one radial direction from the central area to the edge of the implant [Column 5, lines 5-8]. *The reinforced zone extends in multiple (infinite) directions in a swath from about 2 o'clock moving counterclockwise to about 10 o'clock.*

Further regarding Claim 18, Ory's reinforced zone (inside of red lines in Fig. 4 in previous Office Action) is made out of mesh and will have a smaller pore size than the peripheral area of the basic structure (1a). The homogenous central area (yellow in Fig. 4) in the reinforced zone of Ory's implant (1) consists of one mesh laid on top of another piece of mesh [Column 5, lines 5-17]. When adding a sheet of fabric on top of another sheet of fabric, inevitably the fibers of the two fabrics will not line up perfectly, i.e. some of the fibers of the upper fabric will be located above the pores (interstices) of the fabric below, or vice versa. In other words, the pore size will be decreased by the addition of a second sheet of mesh. Therefore, the reinforced zone in Ory's mesh will have a smaller pore size than the peripheral area of the basic structure.

8. Regarding Claim 22, Ory discloses an implant with a weft-knitted or a warp-knitted basic structure [Column 3, lines 50-59].

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 23 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,391,060 to Ory. Ory discloses the claimed invention except the various components of Ory's implant are weft-knitted or warp-knitted *separately*, and then *combined* to form one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to knit the implant [including the basic structure, the reinforced zone and the homogenous central area] in one piece rather than knitting each part separately and combining them, since it has been held that constructing a formerly piecemeal structure in integral form involves only routine skill in the art.
10. Claims 16 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,497,650 to Nicolo in view of U.S. Patent No. 6,162,962 to Hinsch et al. The reinforcing zone of Nicolo's implant lacks such a film/coating. However, Hinsch teaches that it is known that one can apply a resorbable "stiffening material" such as a "film" to the entire surface of an implant [Column 3, lines 35-40] in order to cause the implant to be more firm as well as for purpose of facilitating tissue ingrowth [Column 2, lines 55-63]. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply Hinsch's resorbable film as a coating for Nicolo's implant in order to strengthen the implant and to better facilitate tissue ingrowth.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Response to Arguments

12. Applicant's arguments filed February 27, 2004 have been fully considered but they are not persuasive. Applicant merely added a previously rejected dependent claim (21) into the previously recommended independent claim (18) and added another broad limitation. Applicant claims that the reinforced zone "extends in at least two radial directions from the central area," a limitation that *remains quite broad*. Nowhere does Applicant compare the claimed invention to the prior art, showing how Applicant's invention is novel.

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13. Claim 18, as currently amended, is still quite broad and *remains* rejectable under U.S. Patent Numbers 5,716,409; 6,497,650; and 6,258,124.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Milano
Supervisory Patent Examiner
Art Unit 3731

BCP
BCP
April 27, 2004